UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

04-22933
CIV-ALTONAGA

UNITED STATES OF AMERICA,

Plaintiff,

v.

PROPHARMA, INC., a corporation, and VICTOR G. FARINAS, and REYNALDO G. FARINAS, individuals,

Defendants.

NO. MAGISTRATE JUDGE BANDSTRA

COMPLAINT FOR PERMANENT INJUNCTION

The United States of America, plaintiff, by Peter D. Keisler, Assistant United States Attorney General for the Civil Division, and Marcos Daniel Jimenez, United States Attorney for the Southern District of Florida, respectfully represents to this Honorable Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 332(a), to enjoin defendants Propharma, Inc. ("Propharma"), a corporation, and Victor G. Farinas, and Reynaldo G. Farinas, (hereinafter, collectively, "defendants") from: (a) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); (b) violating 21 U.S.C.

§ 331(k) by causing drugs that defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); (c) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B); (d) violating 21 U.S.C. § 331(k) by causing drugs that defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B); and (e) violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

2. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

4. Defendant Propharma is incorporated under the laws of the State of Florida, and does business at 7760 NW 56th Street and 3307 NW 74th Avenue, Miami, Florida, within the

jurisdiction of this Court. Propharma is engaged in the business of manufacturing, processing, packing, labeling, holding, and distributing over-the-counter ("OTC") and prescription drugs.

5. Defendant Victor G. Farinas is the President and co-owner of Propharma. He has authority over, and responsibility for, all operations at Propharma, including, but not limited to, the manufacture, processing, packing, labeling, holding, and distribution of Propharma's drug products. He performs his duties at 7760 NW 56th Street, Miami, Florida, within the jurisdiction of this Court.

6. Defendant Reynaldo G. Farinas is the Executive Vice-President of Propharma. He is directly responsible for all issues relating to the firm's manufacturing operations, including oversight of operations, marketing, and personnel. He performs his duties at 7760 NW 56th Street, Miami, Florida, within the jurisdiction of this Court.

7. Defendants have been and are now engaged in the business of manufacturing, processing, packing, labeling, holding, and distributing in interstate commerce various OTC and prescription drug products that are drugs within the meaning of 21 U.S.C. § 321(g).

8. FDA has established and published monographs that

identify certain categories of drugs that can be marketed as OTC drugs, provided they comply with specific regulatory criteria. 21 C.F.R. Part 330. Drugs marketed in conformance with these OTC monographs are generally recognized as safe and effective, 21 C.F.R. § 330.1, and can be marketed without the submission and approval of new drug applications ("NDAs").

9. Defendants manufacture, process, pack, label, hold, and distribute several OTC drug products subject to FDA monographs, including the monograph governing "Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over the Counter Use," 21 C.F.R. Part 341 (hereinafter, the "Cough/Cold Monograph").

10. Defendants regularly manufacture drugs using components they receive in interstate commerce and introduce finished drug products into interstate commerce for shipment outside the state of Florida.

11. The United States Food and Drug Administration ("FDA") conducted an inspection of the defendants' facility between March 16 and April 26, 2004 (the "March/April 2004 inspection").

Adulteration

12. The March/April 2004 inspection revealed that the methods used in, and the facilities and controls used for, the manufacture, processing, packing, labeling, holding, and distribution of drugs are not in compliance with current good manufacturing practice ("CGMP") for drugs. See 21 U.S.C. § 351(a)(2)(B); 21 C.F.R. Parts 210 and 211. CGMP is intended to ensure that drug products have the identity, strength, quality, purity, and other attributes necessary for their safe and effective use.

13. As a result of the CGMP violations, the drugs manufactured by the defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B). These CGMP violations include, but are not limited to, the following:

A. Failure to have the firm's quality control unit review drug product production and control records to determine compliance with all established, approved written procedures before a batch of drugs is released or distributed, and failure, whether before or after distribution of the drug products, to thoroughly investigate unexplained discrepancies or the failure of a batch or any of its components to meet any of its specifications, as is required by 21 C.F.R. § 211.192.

B. Failure to establish and follow adequate written procedures for production and process controls designed to assure that their drug products have the identity, strength, quality, and purity they purport or are represented to possess, including failure to have the quality control unit review and approve all such procedures, as is required by 21 C.F.R. § 211.100.

C. Failure to perform appropriate laboratory testing on drug products to assure conformance to specifications, including testing products required to be free of objectionable microorganisms, as is required by 21 C.F.R. § 211.165.

D. Failure to follow written procedures setting forth the responsibilities and procedures applicable to the quality control unit, including adequate investigation of errors identified in production records, as is required by 21 C.F.R. §§ 211.22(a) and (d).

E. Failure to establish and follow appropriate procedures governing the handling of all written and oral complaints received concerning their drug products, as is required by 21 C.F.R. § 211.198.

F. Failure to establish and follow appropriate written procedures designed to prevent objectionable

microorganisms in drug products not required to be sterile, as is required by 21 C.F.R. § 211.113(a).

G. Failure to establish and follow an adequate written stability testing program, as is required by 21 C.F.R. § 211.166.

H. Failure to establish and follow written procedures for cleaning and maintenance of equipment, as is required by 21 C.F.R. § 211.67.

14. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and delivering for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), as set forth in paragraph 14 above.

15. Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration within the meaning of 21 U.S.C. § 351(a)(2)(B) of articles of drug, as defined by 21 U.S.C. § 321(g)(1), as set forth in paragraph 14 above, while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Misbranding

16. The March/April 2004 inspection revealed that several OTC drug products produced by Propharma, including DEKA Cough/Cold Formula, Uni-Hist DM Pediatric Syrup, DECON-

DM, Panatuss DX, TUSSAFED EX, TUSSIPHEN-DM antitussive/ expectorant, and HISDEC Antihistamine/Decongestant, were labeled with the "Rx Only" symbol, despite the fact that these drugs are not prescription drugs. Pursuant to 21 U.S.C. § 353(b)(4)(B), nonprescription drug products that bear the symbol "Rx Only" are deemed misbranded.

17. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B).

18. Defendants violate 21 U.S.C. 331(k), by causing drugs that defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B).

Unapproved New Drugs

19. The March/April 2004 inspection also revealed that several drug products produced by Propharma are unapproved new drugs as follows:

A. Several of Propharma's drug products contain more of a particular ingredient, dextromethorphan hydrobromide, than is permitted in the Cough/Cold Monograph, 21 C.F.R. § 341.74(d)(1)(iii). These drug products are unapproved new drugs under the Act because they are not

generally recognized as safe and effective for the use recommended, prescribed, or suggested in their labeling and they are being marketed by Propharma without FDA approval under 21 U.S.C. § 355.

B. Several of Propharma's drug products contain phenylephrine tannate and chlorpheniramine tannate as active ingredients. These drug products are unapproved new drugs because they are not generally recognized as safe and effective for the use recommended, prescribed, or suggested in their labeling and they are being marketed by Propharma without FDA approval under 21 U.S.C. § 355.

20. Defendants violate 21 U.S.C. 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

History of Violations

21. Propharma has a history of continuing CGMP violations. The CGMP deficiencies present at the March/April 2004 inspection are the same as, or similar to, prior violations observed by FDA during inspections conducted from April 15 to May 5, 2003, January 26 to February 17, 2000, March 18 to 31, 1998, and June 7 to 26, 1995.

22. Propharma's noncompliance has continued in the face of repeated warnings from FDA regarding its CGMP violations. At the close of each of the FDA inspections of Propharma in 2004, 2003, 2000, 1998, and 1995, FDA investigators issued to Propharma officials a detailed List of Inspectional Observations ("Form FDA-483"), which notified Propharma officials of the investigators' observations. The FDA investigators discussed the violations listed in the Form FDA-483s with Propharma officials, and Propharma officials expressed a desire to correct the deficiencies.

23. FDA also issued a Warning Letter to Propharma following the inspection in 1995. The Warning Letter to Propharma emphasized the serious nature of the CGMP violations and alerted Propharma that further regulatory action may result if it did not correct these violations.

24. Although short-lived corrective actions have been noted, primarily during the 2003 inspection, the 2004 inspection demonstrated that the defendants have not been able to maintain Propharma's facilities in a continuous state of CGMP compliance. Despite repeated assurances by Propharma officials, the current CGMP violations are the same as, or similar to, prior violations observed by FDA and brought to the attention of Propharma officials.

25. Plaintiff is informed and believes that, unless restrained by this Court, defendants will continue to violate the Act in the manner set forth herein.

WHEREFORE, Plaintiff prays:

I. That defendants Propharma, Inc., a corporation, and Victor G. Farinas, and Reynaldo G. Farinas, individuals, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be enjoined from manufacturing, processing, packing, labeling, holding, or distributing articles of drug unless and until defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute articles of drug are established, operated, and administered in conformity with CGMP and the Act, in a manner that has been found acceptable by FDA; and

II. That defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of

the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

B. Violating 21 U.S.C. § 331(k) by causing drugs that defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

C. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of § 353(b)(4)(B);

D. Violating 21 U.S.C. § 331(k) by causing drugs that defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 353(b)(4)(B); and

E. Violating 21 U.S.C. 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

III. That FDA be authorized pursuant to this injunction to inspect defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by defendants at the rates prevailing at the time the inspections are accomplished; and

IV. That the Court award plaintiff costs and other such relief as the Court deems just and proper.

DATED this 19th day of November, 2004.

Respectfully submitted,

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